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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/552,705	04/19/00	CHEN	S 2124-311

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EXAMINER	
FRONDA, C	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/552,705	Applicant(s) Chen et al.
	Examiner First Last	Group Art Unit 1234

☒ Responsive to communication(s) filed on *December 8, 2000 (paper no. 6)*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-52* is/are pending in the application.

Of the above, claim(s) *1-42* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *43-52* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. In the **RESPONSE TO RESTRICTION REQUIREMENT** dated December 8, 2000 (paper no. 6), Applicants have elected with traverse the invention of Group IV, claims 43-52. Applicants have elected the following species for 1) a co-regulatory protein, 2) a nuclear receptor or nuclear receptor binding domain and 3) a ligand or hormone: 1) PNRC as the co-regulatory protein, 2) the estrogen receptor, and 3) estradiol.

2. Applicants' arguments filed on December 8, 2000 (paper no. 6) have been fully considered but they are not persuasive. Applicants argue that the assertion in the previous Office Action that the methods of Groups I-IV are patentably distinct inventions requiring different goals, methodologies, products, and technical considerations has no support within M.P.E.P 806.05 and that no explanation was set forth in the previous Office Action explaining the differences between the inventions. Applicants argue that the restriction requirement is improper because the burden of searching is identical regardless of whether a search is done for one of the four groups or all of the groups since all of the pending claims are classified within the same class and subclass. Furthermore, Applicants argue that the method steps of all the claims are nearly identical.

Inventions of Groups I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups 1-IV are distinct both physically and functionally; require different process steps, reagents, and parameters; and produce different products.

Each of the inventions of Groups I-IV have different goals and purposes. As stated in the previous Office Action, Group I is directed toward screening a chemical for its ability to enhance binding of a co-regulatory protein to a ligand binding domain; Group II is directed toward screening for a test chemical to determine if it has activity similar to a known chemical; Group III is directed toward determining a concentration of a ligand or a hormone in a tissue sample; and Group IV is directed toward screening for a protein which interacts with a chemical.

The method of claim 1 of Group I is different from the method in claim 25 of Group II because in part (d) of claim 1 the claimed chemical is selected for being able to enhance binding of the claimed co-regulatory protein to the claimed nuclear receptor or nuclear receptor ligand binding domain while in claim 25 the claimed chemical is selected for having activity that is similar to a known chemical. A search of the methods in the patent literature and the non-patent literature cannot be made without serious burden because these methods have different process

steps that require separate searches which have different limits, boundaries, scope, and subject matter. Specifically, the search of the method of claim 25 would require searching for a known chemical and its activity, the claimed chemical which is sought and its activity, and determining whether the test chemical sought by the method of claim 25 has similar activity to the known chemical; whereas the search of the method of claim 1 would require searching for a test chemical that enhances binding of the claimed co-regulatory protein to the claimed nuclear receptor or nuclear receptor ligand binding domain.

The method of claim 1 of Group I is different from the method of claim 34 of Group III because the method of claim 34 requires "(b) preparing an extract of said tissue sample" which is a process step not recited in claim 1. A search of the methods in the patent literature and the non-patent literature cannot be made without serious burden because these methods have different process steps that require separate searches which have different limits, boundaries, scope, and subject matter. Specifically, the search of the method of claim 34 would require searching for extracts of the claimed tissue sample and the ligand or hormone contained in the claimed extract while the search of the method of claim 1 would require searching for a test chemical that enhances binding of the claimed co-regulatory protein to the claimed nuclear receptor or nuclear receptor ligand binding domain.

The method of claim 1 of Group I is different from the method of claim 43 of Group IV because the method of claim 43 involves contacting a chemical with gene products of the library of nucleic acids expressed in the cotransfected cell and screening for proteins that interacts with the chemical; whereas the method of claim 1 involves contacting a test chemical with the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain and screening for chemicals that enhance binding of the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain. A search of the methods in the patent literature and the non-patent literature cannot be made without serious burden because these methods have different process steps that require separate searches which have different limits, boundaries, scope, and subject matter. Specifically, the search of the method of claim 43 would require searching for the identity of the chemical which interacts with the claimed protein and libraries of nucleic acids to produce a library of cotransfected cells which synthesize the claimed co-regulatory protein while the search of the method of claim 1 would require searching for a test chemical that enhances binding of the claimed co-regulatory protein to the claimed nuclear receptor or nuclear receptor ligand binding domain.

While the inventions of Groups I-IV are classified under the same class and subclass, each of the inventions have acquired a separate status in the art because of their recognized divergent subject matter. Inventions of Groups I-IV are unrelated because these methods constitute patentably distinct inventions requiring different goals, methodologies, and products; they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. Accordingly, restriction is deemed to be proper between

the methods of Groups I-IV

Claims 1-42 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Claims 43-52 are under consideration in this Office Action.

Claim Objections

4. Claims 47 is objected to because of the following informalities: Claim 47 recites non-elected subject matter. Applicant is required to amend the claim to recited the elected subject matter which is the estrogen receptor (ER) and estradiol.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 43-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 43 and 52 are directed to all possible chemicals which promote the binding of the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain. The specification, however, only provides the following representative species of hormones or ligands encompassed by these claims: estradiol, dexoycorticosterone, progesterone, and retionic acid. There is no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification also fails to describe additional representative species of these chemicals by any identifying structural characteristics or properties other than the chemical promoting the binding of the claimed co-regulatory protein and nuclear receptor or nuclear

receptor ligand binding domain for which no predictability of structure is apparent.

Furthermore, Claims 43, 45 and 52 are directed to all possible proteins comprising an amino acid sequence set forth in SEQ ID NO:5 or SEQ ID NO: 9. The specification, however, only provides a single representative species of protein comprising the claimed amino acid sequences: a protein consisting of an amino acid sequence as set forth in SEQ ID NO:8. There is no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification also fails to describe additional representative species of these proteins by any identifying structural characteristics or properties other than the protein having SEQ ID NO: 5 or SEQ ID NO: 9, for which no predictability of structure is apparent.

Given this lack of additional representative species of chemical or protein as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 44-51 which depend from claim 43 are also rejected because they do not correct the defect of claim 43.

7. Claims 43-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein having an amino acid sequence consisting of SEQ ID NO: 8 and the hormone or ligand selected from the group consisting of estradiol, dexoycorticosterone, progesterone, and retionic acid; does not reasonably provide enablement for any chemical or any protein comprising an amino acid sequence set forth in SEQ ID NO:5 or SEQ ID NO: 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, © the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompasses any chemical or any protein comprising an amino acid sequence set forth in SEQ ID NO:5 or SEQ ID NO: 9. The specification provides guidance and examples for using the ligand or hormones selected from the group consisting of estradiol, dexoycorticosterone, progesterone, and retionic acid and a protein having an amino acid sequence consisting of SEQ ID NO:8. While molecular biological techniques and genetic manipulation to make the claimed protein are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological function, biological activity, or utility of a protein comprising SEQ ID NO:5 or SEQ ID NO: 9 or the specific chemical which promotes the binding of the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain is lacking. Thus, searching for the biological

function, biological activity, or utility of said protein or the specific chemical which promotes the binding of the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain is well outside the realm of routine experimentation and predictability in the art of success is extremely low.

The amount of experimentation to determine the biological function, biological activity, or utility of said protein or to determine the specific chemical promoting the binding of the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain is enormous. Such experimentation entails screening a vast number of organisms for a protein comprising the claimed amino acid sequences (SEQ ID NO:5 or SEQ ID NO:8), isolating the gene encoding the protein from libraries prepared from the selected organism, expressing the protein, and determining its biological function, biological activity, or utility. Furthermore, experimentation to determine the specific chemical which promotes the binding of the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain entails screening for and selecting a chemical from a vast number of chemicals and testing each selected chemical for the ability to promote the binding of the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain. Since routine experimentation in the art does not include screening vast numbers proteins having the claimed amino acid sequences or screening chemicals from a vast number of chemicals which promote the binding of the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain, where the expectation of obtaining a desired biological function, biological activity, or utility of the claimed protein or the specific chemical which promotes the binding of the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the structure and function relationship of the claimed protein and the specific chemical which promotes the binding of the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain. Without such a guidance, the experimentation left to those skilled in the art is undue. Claims 44-51 which depend from claim 43 are also rejected because they do not correct the defect of claim 43.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 43-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 and 52 are indefinite because the nature of the interaction claimed between the claimed protein and chemical is not known and has not been defined; and the purpose of . Furthermore, the claims recite a chemical which has not been specifically defined. Claims 42-51 which depend from claim 43 are also rejected because they do not correct the defect of claim 43.

Claim 47 is indefinite because the acronym ER is not defined in the claim.

Conclusion

10. No claim is allowed.

11 The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chen et al. teach a cDNA from human Nk/T cells which codes for a protein with high proline content.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

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PRIMARY EXAMINER